

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT:	Phillips	)	ATTORNEY DOCKET:	03207556
		)		
SERIAL NO.:	10/722184	)	GROUP ART UNIT:	1625
		)		
FILED:	November 25, 2003	)	EXAMINER:	Celia C. Chang
		)		
TITLE:	NOVEL SUBSTITUTED BENZIMIDAZOLE DOSAGE FORMS AND METHOD OF USING SAME			
DATE:	May 25, 2006		CUSTOMER NO.:	26565

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Commissioner for Patents  
PO BOX 1450  
Alexandria, VA 22313-1450

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97(c)**

Applicant hereby submits copies of patents, publications and/or other information of which they are aware and which may be related to the examination of this application, and in respect of which there may be a duty to disclose under 37 CFR § 1.56 and §§ 1.97-1.98, as supplemented by MPEP §609. A list of all enclosed documents is provided in a Form PTO-1449, transmitted herewith. Applicant respectfully requests that the Examiner consider the listed documents and evidence the consideration of relevant portions thereof by making appropriate notations on the attached form.

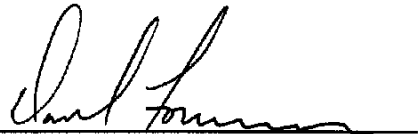
Presentation of documents listed on enclosed Form PTO-1449 is not an admission that any listed document is prior art under the Patent Statutes and the right is reserved to antedate any material described in the listed documents by a showing under 37 C.F.R. § 1.131 or otherwise.

This information disclosure statement is being filed after the period specified in 35 C.F.R. § 1.97(b) but prior to the mailing date of any final action under § 1.113, a

notice of allowance under § 1.311, or an action that otherwise closes prosecution. A fee in the amount of \$180.00 is provided pursuant to 35 U.S.C. 1.17(p).

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR §1.97(g)), an admission that the information cited is or is considered to be material to patentability, or that no other material information exists. Applicant respectfully requests that the statement be considered by the Office in the course of prosecution of the application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David B. Fournier', is written over a horizontal line.

David B. Fournier  
Reg. No. 51,696

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Facsimile: (312) 706-9000

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use as many sheets as necessary)**Complete if Known**

Sheet	1	20	Application Number	10/722,184
			Filing Date	November 25, 2003
			First Named Inventor	Phillips
			Art Unit	1625
			Examiner Name	Celia C. Chang
			Attorney Docket Number	03207556

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number+Kind Code <sup>2</sup> (if known)			
	A1	4045564	08/30/77	Berntsson, et al.	
	A2	4182766	01/08/80	Krasso, et al.	
	A3	4252790	02/24/81	Higuchi	
	A4	4255431	03/10/81	Junggren, et al.	
	A5	4337257	06/29/82	Junggren, et al.	
	A6	4359465	11/16/82	Ruwart	
	A7	4414216	11/08/83	Kawakita, et al.	
	A8	4472409	09/18/84	Senn-Bilfinger	
	A9	4508905	04/02/85	Junggren, et al.	
	A10	4544750	10/01/85	Brandstrom, et al.	
	A11	4738974	04/19/88	Brandstrom, et al.	
	A12	4786505	11/22/88	Lovgren, et al.	
	A13	4853230	08/01/89	Lovgren, et al.	
	A14	4965351	10/23/90	Caruso, et al.	
	A15	4985548	01/15/91	Caruso, et al.	
	A16	4990535	02/05/91	Cho et al.	
	A17	5008278	04/16/91	Brandstrom, et al.	
	A18	5013743	05/07/91	Iwahi, et al.	
	A19	5019584	05/28/91	Brandstrom, et al.	
	A20	5025024	06/18/91	Brandstrom, et al.	
	A21	5039806	08/13/91	Brandstrom, et al.	
	A22	5045321	09/03/91	Makino, et al.	
	A23	5075323	12/24/91	Fain, et al.	
	A24	5093132	03/03/92	Makino, et al.	
	A25	5093342	03/03/92	Tomoi, et al.	
	A26	5106862	04/21/92	Briving, et al.	
	A27	5124158	06/23/92	Ruwart, et al.	
	A28	5215974	06/01/93	Alminger, et al.	
	A29	5294439	03/15/94	Yamaska	
	A30	5339700	08/23/94	Wright, et al.	
	A31	5374730	12/20/94	Slemon, et al.	
	A32	5385739	01/31/95	Debregeas, et al.	
	A33	5386032	01/31/95	Brandstrom	
	A34	5391752	02/21/95	Hoerrner, et al.	
	A35	5395323	03/07/95	Berglund	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO			<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>			Application Number	10/722,184
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			First Named Inventor	Phillips
			Art Unit	1625
			Examiner Name	Celia C. Chang
Sheet	2	20	Attorney Docket Number	03207556

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		Number-Kind Code <sup>2</sup> (if known)			
	A36	5399700	03/21/95	Min, et al.	
	A37	5417980	05/23/95	Goldman, et al.	
	A38	5430042	07/04/95	Lindberg, et al.	
	A39	5447923	09/05/95	Castrenich, et al.	
	A40	5470983	11/28/95	Slemon, et al.	
	A41	5504082	04/02/96	Kawakita, et al.	
	A42	5589491	12/31/96	Nakanishi, et al.	
	A43	5599794	02/04/97	Eek, et al.	
	A44	5629305	05/13/97	Eek, et al.	
	A45	5633244	05/27/97	Eek, et al.	
	A46	5639478	06/17/97	Makino, et al.	
	A47	5690960	11/25/97	Bengtsson, et al.	
	A48	5693818	12/02/97	Von Unge	
	A49	5714504	02/03/98	Lindberg, et al.	
	A50	5714505	02/03/98	Hasselkus	
	A51	5731002	03/24/98	Olovson, et al.	
	A52	5753265	05/19/98	Bergstrand, et al.	
	A53	5762962	06/09/98	Georgiades et al.	
	A54	5766622	06/16/98	Nelson	
	A55	5776765	07/07/98	Graham, et al.	
	A56	5798120	08/25/98	Tomohisa, et al.	
	A57	5814338	09/29/98	Veronesi	
	A58	5817338	10/06/98	Bergstrand, et al.	
	A59	5840737	11/24/98	Phillips	
	A60	5876759	03/02/99	Gowan	
	A61	5877192	03/02/99	Lindberg, et al.	
	A62	5879708	03/09/99	Makino, et al.	
	A63	5883102	03/16/99	Hamley, et al.	
	A64	5885594	03/23/99	Nilsen, et al.	
	A65	5900424	05/04/99	Kallstrom, et al.	
	A66	5929244	07/27/99	Von Unge	
	A67	5939091	08/17/99	Eoga, et al.	
	A68	5948789	09/07/99	Larsson, et al.	
	A69	5955107	09/21/99	Augello, et al.	
	A70	5958955	09/28/99	Gustavsson, et al.	

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			Art Unit	1625
			Examiner Name	Celia C. Chang
Sheet	3	20	Attorney Docket Number	03207556

U.S. PATENT DOCUMENTS					
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		Number-Kind Code <sup>2</sup> (if known)			
	A71	5962022	10/05/99	Bolt, et al.	
	A72	5965162	10/12/99	Fuisz, et al.	
	A73	5972389	10/26/99	Shell, et al.	
	A74	5979515	11/09/99	Olsson	
	A75	6013281	01/11/00	Lundberg, et al.	
	A76	6017560	01/25/00	Makino, et al.	
	A77	6090827	07/18/00	Erickson, et al.	
	A78	6123962	09/26/00	Makino, et al.	
	A79	6124464	09/26/00	Hogberg, et al.	
	A80	6132770	10/17/00	Lundberg	
	A81	6132771	10/17/00	Depui, et al.	
	A82	6136344	10/24/00	Depui, et al.	
	A83	6143771	11/07/00	Lindberg, et al.	
	A84	6147103	11/14/00	Anousis, et al.	
	A85	6150380	11/21/00	Lovqvist, et al.	
	A86	6162816	12/19/00	Bohlin, et al.	
	A87	6166213	12/26/00	Anousis, et al.	
	A88	6183776	02/06/01	Depui, et al.	
	A89	6248363	06/19/01	Patel et al.	
	A90	6274173	08/14/01	Sachs, et al.	
	A91	6284271	09/04/01	Lundberg, et al.	
	A92	2002/0192299	12/19/02	Taneja et al.	
	A93	6569453	04/27/03	Linder et al.	
	A94	5703097	12/30/97	Kim et al.	
	A95	6280773	08/29/01	Cho et al.	
	A96	2005/0370370	02/17/06	Warren	
	A97	6749867	06/15/04	Robinson	

FOREIGN PATENT DOCUMENTS							
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		Country Code <sup>2</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)					
	B1	CA 1234118	03/15/88				
	B2	CA2378018	01/18/01				
	B3	CA2432184	07/11/02				
	B4	DK 19752843	07/01/99	(missing)			

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		Examiner Name	Celia C. Chang	
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		Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)				
	B5	GB 2189698	11/04/87			
	B6	EP 0005129	10/31/79			
	B7	EP 0244380	11/04/87			
	B8	EP 0247983	12/02/87			
	B9	EP 0308515	03/29/89			
	B10	EP 0315964	05/17/89			
	B11	EP 0394471	10/31/90			
	B12	EP 0414847	03/06/91			
	B13	EP 0436620	07/17/91			
	B14	EP 0452697	10/23/91			
	B15	EP 0465254	01/08/92			
	B16	EP 0480691	04/15/92			
	B17	EP 0237200	07/01/92			
	B18	EP 0496437	07/29/92			
	B19	EP 0502556	09/09/92			
	B20	EP 0338861	01/20/93			
	B21	EP 0248634	07/21/93			
	B22	EP 0565210	10/13/93			
	B23	EP 0567201	10/27/93			
	B24	EP 0567643	11/03/93			
	B25	EP 0587659	03/23/94			
	B26	EP 0636364	02/01/95			
	B27	EP 0652751	05/17/95			
	B28	EP 0654471	05/24/95			
	B29	EP 0696921	02/21/96			
	B30	EP 1004305	05/21/00			
	B31	ES 2024993	12/31/90			
	B32	JP 48 103567	12/25/73			
	B33	JP 49 005967	01/19/74			
	B34	JP 49 013172	02/05/74			
	B35	JP 49 020173	02/22/74			
	B36	JP 49 020174	02/22/74			
	B37	JP 49 041198	07/11/74			
	B38	JP 49 093537	09/05/74			
	B39	JP 49 095997	09/11/74			
1334284.1			Date Considered			

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		Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)				
	B40	JP 50 052065	05/09/75			
	B41	JP 50 112373	09/03/75			
	B42	JP 50 142565	11/17/75			
	B43	JP 51 016669	02/10/76			
	B44	JP 51 131875	11/16/76			
	B45	JP 52 005769	01/17/77			
	B46	JP 52 014776	02/03/77			
	B47	JP 52 097978	08/17/77			
	B48	JP 52 102416	08/27/77			
	B49	JP 53 059675	05/29/78			
	B50	JP 55 019211	05/24/80			
	B51	JP 56 061311	05/26/81			
	B52	JP 61 221117	10/01/86			
	B53	JP 62 145083	06/29/87			
	B54	JP 62 258316	11/10/87			
	B55	JP 62 258320	11/10/87			
	B56	JP 62 277322	12/02/87			
	B57	JP 62 283964	12/09/87			
	B58	JP 02 022225	01/25/90			
	B59	JP 03 163018	11/20/90			
	B60	JP 03 034967	02/14/91			
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	B64	JP 05 194225	08/03/93			
	B65	JP 05 255088	10/05/93			
	B66	JP 05 294831	11/09/93			
	B67	JP 06 092853	04/05/94			
	B68	JP 06 100449	04/12/94			
	B69	JP 07 033659	02/03/95			
	B70	JP 09 087110	03/31/97			
	B71	JP 10 017470	01/20/98			
	B72	JP 10 017471	01/20/98			
	B73	JP 2000212180	08/02/00			
	B74	JP 2000355540	12/26/00			
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Sheet	6	20	Attorney Docket Number	03207556

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, Lines, Where Relevant Passages or Relevant Figures Appear	Columns, Where Relevant Figures Appear
		Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>4</sup> (if known)				
	B75	KR 9603605	03/20/96			
	B76	KR 9611238	08/21/96			
	B77	KR 9611390	08/22/96			
	B78	RO 88351	04/30/86			
	B79	WO 9204898	04/02/92			
	B80	WO 9208716	05/29/92			
	B81	WO 9305770	04/01/93			
	B82	WO 9400112	01/06/94			
	B83	WO 9402140	02/03/94			
	B84	WO 9402141	02/03/94			
	B85	WO 9501783	01/19/95			
	B86	WO 9507913	03/23/95			
	B87	WO 9515962	06/15/95			
	B88	WO 9523594	09/08/95			
	B89	WO 9532957	12/07/95			
	B90	WO 9532959	12/07/95			
	B91	WO 9601612	01/25/96			
	B92	WO 9601622	01/25/96			
	B93	WO 9601623	01/25/96			
	B94	WO 9601624	01/25/96			
	B95	WO 9601625	01/25/96			
	B96	WO 9602236	02/01/96			
	B97	WO 9616959	06/06/96			
	B98	WO 9624338	08/15/96			
	B99	WO 9624375	08/15/96			
	B100	WO 9638175	12/05/96			
	B101	WO 9702020	01/23/97			
	B102	WO 9702021	01/23/97			
	B103	WO 9709964	03/20/97			
	B104	WO 9725030	07/17/97			
	B105	WO 9725064	07/17/97			
	B106	WO 9725065	07/17/97			
	B107	WO 9725066	07/17/97			
	B108	WO 9741114	11/06/97			

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)			Application Number	10/722,184
			Filing Date	November 25, 2003
			First Named Inventor	Phillips
			Art Unit	1625
			Examiner Name	Celia C. Chang
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	B109	WO 9748380	12/24/97			
	B110	WO 9800114	01/08/98			
	B111	WO 9802368	01/22/98			
	B112	WO 9816228	04/23/98			
	B113	WO 9828294	07/02/98			
	B114	WO 9840054	09/17/98			
	B115	WO 9850019	11/12/98			
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	B125	WO 9932091	07/01/99			
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	B129	WO 9955705	11/04/99			
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	B132	WO 0010999	03/02/00			
	B133	WO 0015195	03/23/00			
	B134	WO 0026185	05/11/00			
	B135	WO 0027366	05/18/00			
	B136	WO 0028975	05/25/00			
	B137	WO 0030612	06/02/00			
	B138	WO 0035448	06/22/00			
	B139	WO 0044744	08/03/00			
	B140	WO 0045817	08/10/00			
	B141	WO 0050038	08/31/00			
	B142	WO 0069438	11/23/00			

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	B143	WO 0078293	12/28/00			
	B144	WO 0103707	01/18/01			
	B145	WO 0124780	04/12/01			
	B146	WO 0134573	05/17/01			
	B147	WO 03017980	03/06/03			

NON PATENT LITERATURE		
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	C1	Antacid Bottle Instruction
	C2	AL-ASSI, et al., "Treatment of Helicobacter Pylori Infection With Omeprazole-Amoxicillin Combination Therapy Versus Ranitidine/Sodium Bicarbonate-Amoxicillin", <u>The American Journal of Gastroenterology</u> , Vol. 90, No. 9, pp. 1411-14 (September 1995).
	C3	ANDERSSON, et al., "Pharmacokinetic Studies With Esomeprazole, the (S)-Isomer of Omeprazole", <u>Clinical Pharmacokinetics</u> , Vol. 40, No. 6, pp. 411-426 (2001).
	C4	ANDERSSON, T., "Pharmacokinetics, Metabolism and Interactions of Acid Pump Inhibitors: Focus on Omeprazole, Lansoprazole and Pantoprazole", <u>Clin. Pharmacokinet.</u> , Vol. 31, No. 1, pp. 9-28 (July 1996).
	C5	ANDERSSON, T., et al., "Pharmacokinetics and Bioavailability of Omeprazole After Single and Repeated Oral Administration in Healthy Subjects", <u>Br. J. Clin. Pharmac.</u> , Vol. 29, pp. 557-563 (1990).
	C6	ANDERSSON, T., et al., "Pharmacokinetics of [ <sup>14</sup> C]Omeprazole in Patients with Liver Cirrhosis", <u>Clin Pharmacokinet.</u> , Vol. 24, No. 1, pp. 71-78 (1993).
	C7	ANDERSSON, T., et al., "Pharmacokinetics of Various Single Intravenous and Oral Doses of Omeprazole", <u>European Journal of Clinical Pharmacology</u> , Vol. 39, pp. 195-197 (1990).
	C8	ARVIDSSON, et al., "Peak Distortion in the Column Liquid Chromatographic Determination of Omeprazole Dissolved in Borax Buffer", <u>Journal of Chromatography</u> , Vol. 586, Part 2, pp. 271-276 (1991).
	C9	BALABAN, D., et al., "Nasogastric Omeprazole: Effects on Gastric pH in Critically Ill Patients", <u>The American Journal of Gastroenterology</u> , Vol. 92, No. 1, pp. 79-83 (1997).
	C10	BALLARD, E., et al., "Bioequivalence Between Lansoprazole Sachet for Suspension and Intact Capsule," <u>Gastroenterology</u> , Vol. 120 (No. %, Suppl. 1), pg. A-245 (2001).
	C11	BALLESTEROS, et al., "Bolus or Intravenous Infusion of Rantidine: Effects on Gastric pH and Acid Secreation. A Comparison of Relative Efficacy and Cost", <u>Annals of Internal Medicine</u> , Vol. 112, No. 5, pp. 334 - 339 (1990).

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	10/722,184	
		Filing Date	November 25, 2003	
		First Named Inventor	Phillips	
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		Examiner Name	Celia C. Chang	
Sheet	9	20	Attorney Docket Number	03207556

NON PATENT LITERATURE		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C12	BARIE & HARIRI, "Therapeutic Use of Omeprazole For Refractory Stress-Induced Gastric Mucosal Hemorrhage", <u>Critical Care Medicine</u> , Vol. 20, No. 6, pp. 899-901 (1992).
	C13	BEEKMAN, S. M., "Preparation and Properties of New Gastric Antacids I", <u>J. Pharm Assoc</u> , Vol. 49, pp. 191-200, (1960).
	C14	Bennett & Dickson, eds., "Gastrointestinal Drugs", <u>The American Medical Association Drug Evaluation</u> , Vol. 2, The American Medical Association, Chicago, Vol 1:8.
	C15	BLUM, A., "Therapeutic Approach to Ulcer Healing," <u>The American Journal of Medicine</u> , Volume 79 (Suppl. 2C), pp.8-14 (August 30,1985)
	C16	BONE, "Let's Agree on Terminology: Definition of Sepsis", <u>Critical Care Medicine</u> , Vol. 19, No. 7, pp. 973-976 (July 1991).
	C17	BORELLA, et al., Abstract for "Gastric Antisecretory and Anitular/Cytoprotective Effects of 2-cyano-3(ethylthio-3methylthio)-2-Propenoic Acid Methyl Ester", Wyeth-Ayerst Res., Inc. (1989)
	C18	BORRERO, et al., "Antacids vs. Sucralfate in Preventing Acute Gastrointestinal Tract Bleeding in Abdominal Aortic Surgery. A Randomized Trial in 50 Patients", <u>Arch. Surg.</u> , Vol. 121, pp. 810-12 (July 1986).
	C19	BRUNTON, "Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", <u>The Pharmacologic Basis of Therapeutics</u> , p. 897-913 (1990).
	C20	CANTU & KOREK, "Central Nervous System Reactions to Histamine-2 Receptor Blockers", <u>Annals of Internal Medicine</u> , Vol. 114, No. 12, pp. 1027-34 (1991).
	C21	CAOS, A., et al., "Rabeprazole for the Prevention of Pathologic and Symptomatic Relapse of Erosive or Ulcerative Gastroesophageal Reflux Disease", <u>The American Journal of Gastroenterology</u> , Vol. 95, No. 11, pp. 3081-3088 (2000).
	C22	CARROLL, M., et al., "Nasogastric Administration of Omeprazole for Control of Gastric pH" 10 <sup>th</sup> World Congresses of Gastroenterology, Abstracts (October 2-7, 1994).
	C23	CEDERBERG, C., et al., "Omeprazole: Pharmacokinetics and Metabolism in Man", <u>Scand. J. Gastroenterol.</u> , Vol. 24, Suppl. 166, pp. 33-40 (1989).
	C24	CEDERBERG, et al., "Effect of Once Daily Intravenous and Oral Omeprazole on 24-Hour Intra gastric Acidity in Healthy Subjects", <u>Scand. J. Gastroenterol.</u> , Vol. 28, No. 2, pp. 179-184 (February 1993).
	C25	CHING, et al., "Antacids - Indications and Limitations", <u>Drugs</u> , Vol. 47, No. 2, pp. 305-317 (February 1994).
	C26	CIOFFI, et al., "Comparison of Acid Neutralizing and Non-acid Neutralizing Stress Ulcer Prophylaxis in Thermally Injured Patients", <u>The Journal of Trauma</u> , Vol. 36, pp. 541-47 (1994).
	C27	COOK, et al., "Nosocomial Pneumonia and the Role of Gastric pH: A Meta Analysis", <u>Chest</u> , Vol. 100, No. 1, pp. 7-13 (July 1991).
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	C28	COOK, et al., "Risk Factors For Gastrointestinal Bleeding in Critically Ill Patients. Canadian Critical Care Trial Groups", <u>The New England Journal of Medicine</u> , Vol. 330, No. 6, pp. 377-81 (February 10, 1994).
	C29	COOK, et al., "Stress Ulcer Prophylaxis in the Critically Ill: A Meta Analysis", <u>The American Journal of Medicine</u> , Vol. 91, pp. 519-527 (November 1991).
	C30	CRILL, et al., "Upper Gastrointestinal Tract Bleeding in Critically Ill Pediatric Patients", <u>Pharmacotherapy</u> , Vol. 19, No. 2, pp. 162-180 (February 1999).
	C31	CZAJA, et al., "Acute Gastroduodenal Disease After Thermal Injury: An Endoscopic Evaluation of Incidence and Natural History", <u>The New England Journal of Medicine</u> , Vol. 291, pp. 925-929 (October 31, 1974).
	C32	DEAKIN, et al., "Therapeutic Progress - Review XXXIII: Are We Making Progress In The Drug Treatment of Oesophageal Disease?", <u>Journal of Clinical Pharmacy and Therapeutics</u> , Vol. 13, No. 6, pp. 365-374 (December 1988).
	C33	DI IORIO, et al., "Aluminum and Phosphorus Urinary Excretion After Modifying Gastric Acid Secretion In Normal Subjects", <u>Trace Elements and Electrolytes</u> , Vol. 13, No. 1, pp. 47-49 (1996).
	C34	DIGIACINTO, et al., "Stability of Suspension Formulations of Lansoprazole and Omeprazole Stored in Amber-Colored Plastic Oral Syringes", <u>Annals of Pharmacotherapy</u> , Vol. 34, No. 5, pp. 600-605 (May 2000).
	C35	DOAN, et al., "Comparative Pharmacokinetics and Pharmacodynamics of Lansoprazole Oral Capsules and Suspension in Healthy Subjects", <u>American Journal of Health-System Pharmacists</u> , Vol. 58, No. 16, pp. 1512-19 (August 15, 2001).
	C36	DOBKIN, et al., "Does pH Paper Accurately Reflect Gastric pH?", <u>Critical Care Medicine</u> , Vol. 18, pp. 985-88 (September 1990).
	C37	DRIKS, et al., "Nosocomial Pneumonia in Intubated Patients Given Sucralfate As Compared With Antacids or Histamine Type 2 Blockers. The Role of Gastric Colonization", <u>New England Journal Medicine</u> , Vol. 317, pp. 1376-82 (1987).
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	C39	EPKE, A., et al., "Effect of Various Salts on the Stability of Lansoprazole, Omeprazole, and Pantoprazole as Determined by High-Performance Liquid Chromatography", <u>Drug Development and Industrial Pharmacy</u> , Vol. 25, No. 9, pp. 1057-1065 (1999).
	C40	FABIAN, et al., "Pneumonia and Stress Ulceration in Severely Injured Patients. A Prospective Evaluation of the Effects of Stress Ulcer Prophylaxis", <u>Arch. Surg.</u> , Vol. 128, p. 185-91 (1993).

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	C41	FELLENUS, et al., "Substituted Benzimidazoles Inhibit Gastric Acid Secretions by Blocking H+/K+-ATPase", <u>Nature</u> , Vol. 290, Part 5802, pp. 159-61 (1981).
	C42	FERRON et al., "Oral Bioavailability of Pantoprazole Suspended in Sodium Bicarbonate Solution", <u>Am J Health-Syst Pharm</u> , Vol. 60, pp. 1324-1328 (July 1, 2003)
	C43	FIDDIAN-GREEN, et al., Predictive Value of Intramural pH and Other Risk Factors For Massive Bleeding From Stress Ulceration", <u>Gastroenterology</u> , Vol. 85, No. 3, pp. 613-20 (1983).
	C44	FITTON, A., et al., "Pantoprazole, A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders", <u>Drugs</u> , Vol. 51, No. 3, pp. 460-482 (March 1996).
	C45	FRYKLUND, et al., "Function and Structure of Parietal Cells After H+/K+-ATPase Blockade, <u>American Journal of Physiology</u> , Vol. 254, pp. G399-407 (1988).
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	C52	HATLEBAKK, J., et al., "Lansoprazole Capsules and Amoxicillin Oral Suspension in the Treatment of Peptic Ulcer Disease", <u>Scand. J. Gastroenterol.</u> , Vol. 30, No. 11, pp. 1053-57 (1995).
	C53	HEATH, et al., "Intragastric pH Measurement Using a Novel Disposable Sensor", <u>Intensive Care Medicine</u> , Vol. 14, No. 3, pp. 232-35 (1988).
	C54	HIXSON, et al., "Current Trends in the Pharmacotherapy for Gastroesophageal Reflux Disease", <u>Arch. Intern. Med.</u> , Vol. 152, No. 4, pp. 717-723 (April 1992).
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	10/722,184
Filing Date	November 25, 2003
First Named Inventor	Phillips
Art Unit	1625
Examiner Name	Celia C. Chang
Attorney Docket Number	03207556

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**NON PATENT LITERATURE**

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C56	HOLBERT, J., et al., "A Study of Antacid Buffers: I. The Time Factor in Neutralization of Gastric Acidity", <u>Journal of The American Pharmaceutical Association (Scientific Edition)</u> , Vol. 36, pp. 149-151 (1947).
	C57	HOLT, S., et al., "Omeprazole, Overview and Opinion", <u>Digestive Diseases and Sciences</u> , Vol. 36, No. 4, pp. 385-393 (April 1991).
	C58	HORN, J., "The Proton-Pump Inhibitors: Similarities and Differences", <u>Clinical Therapeutics</u> , Vol. 22, No. 3, pp. 266-280 (2000).
	C59	HOWDEN, et al., "Oral Pharmacokinetics of Omeprazole", <u>European Journal of Clinical Pharmacology</u> , Vol. 26, pp. 641-643 (1984).
	C60	HUMPHRIES, et al., "Review Article: Drug Interactions With Agents Used to Treat Acid-Related Diseases", <u>Alimentary Pharmacology &amp; Therapeutics</u> , Vol. 13, Suppl. 3, pp. 18-26 (August 1999).
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	C67	KROMER, et al., "Differences in pH-Dependent Activation Rate of Substituted Benzimidazoles and Biological in vitro Correlates", <u>Pharmacology</u> , Vol. 56, pp. 57-70, (1998)
	C68	LAGGNER, et al., "Prevention of Upper Gastrointestinal Bleeding in Long Term Ventilated Patients", <u>American Journal of Medicine</u> , Vol. 86, Suppl. 6A, pp. 81-84 (June 9, 1989).
	C69	LANDAHL, S., et al., "Pharmacokinetic Study of Omeprazole in Elderly Healthy Volunteers", <u>Clin. Pharmacokin.</u> , Vol. 23, No. 6, pp. 469-476 (1992).
	C70	LARSON, C., et al., "Bioavailability and Efficacy of Omeprazole Given Orally and By Nasogastric Tube", <u>Digestive Diseases and Sciences</u> , Vol. 41, No. 3, pp. 475-479 (March 1996).

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		Art Unit	1625	
		Examiner Name	Celia C. Chang	
Sheet	13	20	Attorney Docket Number	03207556

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	C71	LARSON, et al., "Gastric Response to Severe Head Injury", <u>American Journal of Surgery</u> , Vol. 147, pp. 97-105 (January 1984).
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	C73	LASKY, M., et al., "A Prospective Study of Omeprazole Suspension to Prevent Clinically Significant Gastrointestinal Bleeding From Stress Ulcers in Mechanically Ventilated Trauma Patients", <u>The Journal of Trauma: Injury Infection, and Critical Care</u> , Vol. 44, No. 3, pp. 527-533 (March 1998).
	C74	LIN, M., et al., "Evaluation of Buffering Capacity and Acid Neutralizing pH Time Profile of Antacids", <u>J Formos Med Assoc</u> , Vol. 97, No. 10, pp. 704-710 (1998).
	C75	LIND, et al., "Inhibition of Basal and Betazole - and Sham-Feeding-Induced Acid Secretion by Omeprazole in Man", <u>Scand. J. Gastroenterol</u> , Vol. 21, No. 8, pp. 1004-1010 (1986).
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	C80	MARTIN, A., et al., <u>Physical Pharmacy - Physical Chemicals Principles in the Pharmaceutical Sciences</u> , Fourth Edition, (1993)
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	C85	MEINERS, et al., "Evaluation of Various Techniques to Monitor Intragastric pH", <u>Arch. Surg.</u> , Vol. 117, No. 3, pp. 288-91 (1982).
	C86	METZLER, M., Advances in the use of PPI's From Efficacy to Effectiveness, <u>Presentation: Simplified Omeprazole Suspension</u> (1999).
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	C88	NAKAGAWA, et al., "Lansoprazole - Phase I Study of Lansoprazole (AG-1749) - Antiulcer Agent", <u>Journal of Clinical Therapeutics &amp; Medicines</u> , Vol. 7, No. 1, pp. 33-50 (1991).
	C89	NAKAMURA, M, et al., "Effect of Combined Administration of Lansoprazole and Sofalcone on Microvascular and Connective Tissue Regeneration After Ethanol-induced Mucosal Damage", <u>Journal of Clinical Gastroenterology</u> , Vol. 27, Supp. 1, pp. 170-77 (1998).
	C90	NAUNTON, M., et al., "Overuse of Proton Pump Inhibitors", <u>Journal of Clinical Pharmacy and Therapeutics</u> , Vol. 25, pp. 333-340 (2000).
	C91	OH & CARROLL, "Electrolyte and Acid-base Disorders", <u>The Pharmacologic Approach to the Critically Ill Patient</u> , pp. 957-68 (Chernow, B. ed. 1994).
	C92	OOSTERHUIS, et al. "Omeprazole: Pharmacology, Pharmacokinetics and Interactions", <u>Digestion</u> , Vol. 44, Suppl. 1, pp. 9-17 (1989).
	C93	OSLER, et al., "Effect of Omeprazole On The Phosphate-Binding Capacity of Calcium Carbonate", <u>Nephron</u> , Vol. 69, pp. 89-90 (1995).
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	C95	PAUL, J., et al., "Pantoprazole Bicarbonate Suspension (PBS) Provides Oral Bioavailability Comparable To Tablet", <u>Critical Care Medicine</u> , (Feb. 2001).
	C96	PECKMAN, H., "Alternative method for administering proton-pump inhibitors through nasogastric tubes" <u>Am J Health-Syst Pharm</u> Vol. 56, pp. 1020, (May 15 1999).
	C97	PEURA & JOHNSON, "Cimetidine for Prevention and Treatment of Gastroduodenal Mucosal Lesions in Patients In an Intensive Care Unit", <u>Ann. Intern. Med.</u> , Vol. 103, pp. 173-177 (1985).
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	C100	PHILLIPS, J., et al., "A Multicenter, Prospective, Randomized Clinical Trial of Continuous Infusion I.V. Ranitidine vs. Omeprazole Suspension in the Prophylaxis of Stress Ulcers", <u>Critical Care Medicine</u> , Vol. 26, No. 1 (Suppl.), p. A101, No. 222 (1998).

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	C101	PHILLIPS, J., et al., "A Prospective Study of Simplified Omeprazole Suspension for the Prophylaxis of Stress-related Mucosal Damage", <u>Critical Care Medicine</u> , Vol. 24, No. 11, pp. 1793-1800 (1996).
	C102	PHILLIPS, J., et al., "Simplified Omeprazole Solution For The Prophylaxis of Stress-Related Mucosal Damage In Critically Ill Patients", <u>Critical Care Medicine</u> , Vol. 22, No. 1, p. A53 (January 1994).
	C103	PHILLIPS, J., et al., "The Stability of Simplified Lansoprazole Suspension (SLS)", <u>Gastroenterology</u> , Vol. 116, No. 4, pg. G0382 (April 1999).
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	C108	PHILLIPS, J., Presentation: "Stress-related Mucosal Damage, Optimizing Drug Therapy, <u>Prophylaxis of Stress Ulcers</u> , (1997)
	C109	PHILLIPS, J., Presentation: "Stress-related Mucosal Damage, Optimizing Drug therapy in the 1990's, <u>The University of Missouri Surgical Society Scientific Program</u> , (June 1994).
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	C111	PHILLIPS, Project #5122: "Simplified Omeprazole Solution (S.O.S.) - Pharmacokinetic/Pharmacodynamic Study in Patients at Risk for Stress Related Mucosal Damage (SRMD)" (Approved 4/28/94).
	C112	PHILLIPS, J. et al., " <u>Flavored lansoprazole Suspension in Pediatric Gerd.</u> ", <u>Journal of Pediatric Gastroenterology and Nutrition</u> , Vol. 31, Supp. 2 (December 2000)
	C113	PHILLIPS, J. et al., Abstract of " <u>A Randomized, Cross-over Study of Duodenal or Jejunal Compared to Nasogastric Administration of Omeprazole Suspension in Critically Ill Patients</u> ", <u>Pharmacotherapy, The Journal of Human Pharmacology and Drug Therapy</u> , pp. 1237 (October 6, 2000)
	C114	PHILLIPS, J. et al., " <u>Use of Flavored Lansoprazole or Omeprazole Suspensions in Pediatric Gerd.</u> ", Supplement to <u>Gastroenterology</u> , Vol. 18 (April 2000)
	C115	PHILLIPS, J. et al., Abstract for " <u>A Randomized, Crossover Study of Duodenal or Jejunal Compared to Nasogastric Administration of Omeprazole Suspension in Critically Ill Patients</u> ", <u>The Journal of Human Pharmacology and Drug Therapy</u> , Vol. 20, Number 10, p. 1237 (October 2000)
	C116	PHILLIPS, J. et al., " <u>Use of Flavored Lansoprazole or Omeprazole Suspensions in Pediatric Gerd</u> ", <u>Supplement to Gastroenterology</u> , (May 2000)
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	C117	PICKWORTH, et al., "Occurrence of Nosocomial Pneumonia in Mechanically Ventilated Trauma Patients: A Comparison of Sucralfate and Ranitidine", <u>Critical Care Medicine</u> , Vol. 21, No. 12, , pp. 1856-62 (1993).
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	C130	ROY, P., et al., "Zollinger-Ellison Syndrome - Clinical Presentation in 261 Patients", <u>Medicine</u> , Vol. 79, No. 6, pp. 379-411 (2000).
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	10/722,184	
		Filing Date	November 25, 2003	
		First Named Inventor	Phillips	
		Art Unit	1625	
		Examiner Name	Celia C. Chang	
Sheet	17	20	Attorney Docket Number	03207556

NON PATENT LITERATURE		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C133	SCHEPP, "Stress Ulcer Prophylaxis: Still a Valid Option in the 1990s?", <u>Digestion</u> , Vol. 54, No. 4, pp. 189-99 (1993).
	C134	SCHMASSMANN, et al., "Antacid Provides Better Restoration of Glandular Structures Within the Gastric Ulcer Scar Than Omeprazole", <u>Gut</u> , Vol. 35, No. 7, pp. 896-904 (July 1994).
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use as many sheets as necessary)**Complete if Known**

Sheet	18		20	Application Number	10/722,184
				Filing Date	November 25, 2003
				First Named Inventor	Phillips
				Art Unit	1625
				Examiner Name	Celia C. Chang
				Attorney Docket Number	03207556

**NON PATENT LITERATURE**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C146	SHARMA, V., "Comparison of 24-hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole", <u>American Journal of Health-System Pharmacists</u> , Vol. 56, Suppl 4, pp. S18-S21(December 1, 1999).
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		Art Unit	1625	
		Examiner Name	Celia C. Chang	
Sheet	19	20	Attorney Docket Number	03207556

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	C160	THOMSON, "Are The Orally Administered Proton Pump Inhibitors Equivalent? A Comparison of Lansoprazole, Omeprazole, Pantoprazole, and Rabeprazole", <u>Current Gastroenterology Reports</u> , Vol. 2, No. 6, pp. 482-493 (December 2000).
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	C162	TRYBA, "Risk of Acute Stress Bleeding and Nosocomial Pneumonia in Ventilated Intensive Care Patients. Sucralfate vs. Antacids", <u>American Journal of Medicine</u> , Vol. 87 (3B) 117-24 (1987).
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	C165	VIAL, et al., "Side Effects of Ranitidine", <u>Drug Safety</u> , Vol. 6, pp. 94-117 (March/April 1991).
	C166	VINCENT, et al., "Concurrent Administration of Omeprazole and Antacid Does Not Alter The Pharmacokinetics and Pharmacodynamics Of Dofetilide in Healthy Subjects", <u>Clinical Pharmacology &amp; Therapeutics</u> , Vol. 59, No. 2 (P11-93), pg. 182 (February 1996).
	C167	WADE, Organic Chemistry, Pritice-Hall, Inc., Chapter 8, p. 349 (1987).
	C168	WALAN, "Pharmacological Agents For Peptic Ulcer Disease", <u>Scand. J. Gastroenterol. Suppl.</u> , Vol. 19, No. 98, pg. 1 (1984).
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	C172	WILDER-SMITH & MERKI, "Tolerance During Dosing with H <sub>2</sub> Receptor Antagonists: An Overview", <u>Scand. J. Gastroenterol.</u> , Vol. 193, pp. 14-19 (1992).
	C173	YAMAKAWA, T., "Synthesis and Structure-Activity Relationships of Substituted 2-[2-imidazolylsulfenyl)methyl] Anilines As A New Class of Gastric H <sup>+</sup> /K <sup>+</sup> -ATPase Inhibitors. II.", <u>Chem Pharm Bull</u> (Tokyo), Vol. 40, No. 3, pp. 675-682 (March 1992).

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			First Named Inventor	Phillips	
			Art Unit	1625	
			Examiner Name	Celia C. Chang	
Sheet	20		20	Attorney Docket Number	03207556

<b>NON PATENT LITERATURE</b>		
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	C174	YASUDA, et al., "Antacids Have No Influence on the Pharmacokinetics of Rabeprazole, A New Proton Pump Inhibitor, In Healthy Volunteers", <u>International Journal of Clinical Pharmacology and Therapeutics</u> , Vol. 37, No. 5, pp. 249-253 (1999).
	C175	ZINNER, et al., "The Prevention of Upper Gastro-Intestinal Tract Bleeding in Patients in an Intensive Care Unit", <u>Surgery, Gynecology and Obstetrics</u> , Vol. 153, pp. 214-20 (August 1981).

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